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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/578,239	05/24/2000	Nitya Anand	RLL-5.4DIV	6447

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EXAMINER

WRIGHT, SONYA N

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 05/30/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/578,239

**Applicant(s)**

ANAND ET AL.

**Examiner**

Sonya Wright

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 44, 45, 48 and 49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 44, 45, 48, and 49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_

### DETAILED ACTION

This Office Action is in response to Applicant's amendment filed March 25, 2003. claims 44 and 45 have been amended. Claims 48 and 49 have been added. Claims 44, 45, 48, and 49 are pending in this application.

The rejections under 35 U.S.C. 102 and 103 have been overcome with Applicant's amendments.

The rejection under 35 U.S.C. 112 has been maintained.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44, 45, 48, and 49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 44, 45, 48, and 49 lack description.

Applicants have not shown description for the phrase "pyridine at reflux temperature followed by reflux in the presence of acetic anhydride". However, the phrase is included in a specific example, i.e. the preparation of compound number 1, therefore the specification does not support the step of "pyridine at reflux temperature followed by reflux in the presence of acetic anhydride" as being useful in the preparation of ALL compounds of claims 44, 45, 48, and 49. Consequently, the phrase phrase

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"pyridine at reflux temperature followed by reflux in the presence of acetic anhydride" in claims 44, 45, 48, and 49 lacks description in the specification.

Claims 44, 45, 48, and 49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

1) Nature of the invention.

The claims are drawn to a process for preparing a compound of the formula (I) which comprises reacting a compound having the structure of Formula VI' with a compound having the structure of formula V in pyridine at reflux temperature followed by reflux in the presence of acetic anhydride thereby to produce the compound of Formula I.

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2) State of the prior art.

The prior arts do not indicate how many of the compounds of Formula I can be made by the instant process. Applicant cites references which teach the synthesis of pyrrolidinedione, piperidine-2,6-dione, and phthalimide compounds in pages 4 and 5.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. The genus of formula (I) encompasses a large number of compounds. Applicant's specification does not enable the public to prepare all of the compounds of formula (I) by the instant process.

4) Level of predictability in the art.

The art pertaining to the preparation of pyrrolidine derivatives remains highly unpredictable. Processes of preparing different types of pyrrolidine derivatives require various experimental procedures and without guidance that is applicable to all possible compounds of formula (I), there would be little predictability in performing the claimed process.

5) Amount of direction and guidance provided by the inventor.

The genus of the formula (I) encompasses a vast number of compounds. Applicant's limited guidance does not enable the public to prepare all compounds of formula (I) by the instant process.

6) Existence of working examples.

The genus of the formula (I) encompasses a vast number of compounds. Applicant provides one example of preparing one compound by the instant process. This example does not enable the public to prepare all of the compounds of formula (I) by the instant process.

7) Breadth of claims.

The claims are extremely broad due to the vast number of possible compounds for formula (I) .

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous amount of modifications to perform in order to obtain compounds of formula (I) as claimed.

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed process without undue experimentation, see *In re Armbruster* 185 USPQ 152 CCPA 1975.

***Response to Arguments***

Applicant's arguments filed March 25, 2003 have been fully considered but they are not persuasive with respect to the rejection of "pyridine at reflux temperature followed by reflux in the presence of acetic anhydride".

Applicant argues that one of ordinary skill in the art would understand that this reaction, taking place "in pyridine at reflux temperature followed by reflux in the presence of acetic anhydride" represents general reaction conditions for transformations described in Scheme II. However, the phrase is included in a specific example, i.e. the

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preparation of compound number 1, therefore the specification does not support the step of "pyridine at reflux temperature followed by reflux in the presence of acetic anhydride" as being useful in the preparation of ALL compounds of claims 44, 45, 48, and 49. Consequently, the phrase phrase "pyridine at reflux temperature followed by reflux in the presence of acetic anhydride" in claims 44, 45, 48, and 49 lacks description in the specification.

Applicant argues that the prior art under discussion in this prosecution (Khadilkar et al.) discloses that the claimed reactions may be carried out using these reagents. However, Khadilkar et al. disclose a process which teaches the use of pyridine and acetic anhydride in examples 4a-4g, and in fact, Khadilkar et al. disclose a process which does not use pyridine and acetic anhydride in the preparation of compounds 3a-3g. (See the preparation of 2-[3-(4-(4-Methylphenyl)-1-piperaziny)propyl]-1H-benz[de]isoquinolin-1,3(2H)dione).

Khadilkar et al. do not indicate that the process for preparing compounds 4a-4g (which uses pyridine and acetic anhydride) is also useful in preparing compounds 3a-3g. Therefore, one of ordinary skill in the art would not assume, from the teachings of Khadilkar et al., that the use of pyridine and acetic anhydride is useful in the preparation of all products of the instantly claimed process.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not



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communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

  
\_\_\_\_\_  
Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

May 23, 2003